§ 5.415 Authority relating to medical device reporting procedures.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH, are authorized to approve electronic reporting under § 803.14 of this chapter.

(b) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH are authorized to request the submission of additional information under § 803.15 of this chapter.

(c) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH are authorized to grant or revoke exemptions and variances from reporting requirements under § 803.19 of this chapter.

(d) These officials may not further redelegate these authorities.

§ 5.416 Medical device tracking.

(a) The following officials are authorized to issue orders under section 519(e) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360i(e)) requiring manufacturers to adopt methods of tracking devices:

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(b) These officials may not further redelegate this authority.

§ 5.417 Authority pertaining to accreditation functions for medical devices.

(a) The following officials are authorized under section 523(a)(1) and (b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m(a)(1) and (b)(2)(A)) to respond to a request for accreditation and to accredit persons for the purpose of reviewing reports submitted under section 510(k) of the act (21 U.S.C. 360(k)) and making recommendations regarding the initial classification of devices:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Health and Industry Programs (OHIP), CDRH.

(3) The Director and Deputy Director, Division of Small Manufacturers Assistance (DSMA), OHIP, CDRH.

(b) The following officials are authorized under section 523(a)(2)(B) and (C) of the act (21 U.S.C. 360m(a)(2)(B) and (C)) to make a determination with respect to the recommendation of an initial classification of a device; and to change the initial classification under section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)) that is recommended by an accredited person to provide to such person, and the person who submitted the report under section 510(k) of the act (21 U.S.C. 360(k)) for the device, a statement explaining in detail the reasons for the change:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(3) The Division Directors and Deputy Division Directors, ODE, CDRH.

(c) The following officials are authorized under section 523(b)(2)(B) of the act (21 U.S.C. 360m(b)(2)(B)) to suspend or withdraw accreditation of any person accredited to review reports and to make recommendations under section 523 of the act (21 U.S.C. 360m):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DSMA, OHIP, CDRH.

(d) The following officials are authorized under section 523(b)(2)(C) of the act (21 U.S.C. 360m(b)(2)(c)) to implement the measures described in that section to ensure that persons accredited under section 523 of the act (21 U.S.C. 360m) will continue to meet the standards of accreditation:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(e) These officials may not further redelegate these authorities.

Subpart G—Animal Drugs; Redelegations of Authority

§ 5.500 Issuance of Federal Register documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use.

The Director and Deputy Director, Center for Veterinary Medicine (CVM) are authorized to issue FEDERAL REGISTER documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use related to implementation of section 512(a)(4) and (5) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b(a)(4) and (5)). These officials may further redelegate this authority.

§ 5.501 Approval of new animal drug applications, medicated feed mill license applications and their supplements.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to the approval of new animal drug applications, and supplements thereto, for new animal drugs submitted under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b).

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to approved new animal drugs submitted under section 512 of the act (21 U.S.C. 360b):

(1) The Director, the Deputy Director for Human Food Safety and Consultative Services, and the Deputy Director for Therapeutic and Production Drug Review, Office of New Animal Drug Evaluation, CVM.

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(c) The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of supplemental applications to new animal drug applications that are described by section 514.8(a)(4)(iii), (iv), and (v), and (d)(3) of this chapter.

(1) The Director, Division of Manufacturing Technologies, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Epidemiology and Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of medicated feed mill license applications for the manufacture of animal feeds containing new animal drugs under section 512(m) of the act (21 U.S.C. 360b(m), as amended by the Animal Drug Availability Act of 1996 (Public Law 104–250):

(1) The Director and Deputy Director, CVM.

(2) The Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Leader, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(4) The Medicated Feeds Specialist, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(e) These officials may not further redelegate these authorities.

§ 5.502 Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to:

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and proposals to refuse approval or to revoke approval of medicated feed mill license applications, and supplements thereto, submitted under section 512(m) of the Federal Food, Drug, and